

TRANSMITTAL LETTER THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER

719 CT/US

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR

09/486839

INTERNATIONAL APPLICATION NO.  
PCT/US98/18953INTERNATIONAL FILING DATE  
11 SEPT 1998PRIORITY DATE CLAIMED  
11 SEPT 1997

TITLE OF INVENTION

INTRANASAL FORMULATION CONTAINING SCOPOLAMINE AND METHOD OF TREATING MOTION  
SICKNESS

APPLICANT(S) FOR DO/EO/US

ACHARI, Raja G.; BEHL, Charanjit R.; CHOWHAN, Prafulla K.; DE MEIRELES, C. Jorge; DUA, Ramneik;  
ROMEO, Vincent D.; SILENO, Anthony P.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
  - a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ has been transmitted by the International Bureau.
  - c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☐ A copy of the International Search Report (PCT/ISA/210).
8. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
  - a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
  - b. ☐ have been transmitted by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☒ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☒ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

## Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☒ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☐ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☒ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

- Letter of Clarification regarding submission of a copy of declaration.

428 Rec'd PCT/PTO 01 MAR 2000

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR 1.492(a)(1)-(5)) : 09/486839

INTERNATIONAL APPLICATION NO. PCT/US98/18953

ATTORNEY'S DOCKET NUMBER 719-75 PCT/US

CALCULATIONS PTO USE ONLY

21. The following fees are submitted:

- BASIC NATIONAL FEE ( 37 CFR 1.492 (a) (1) - (5)) :**
- ☐ Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... \$970.00
  - ☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... \$840.00
  - ☐ International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$690.00
  - ☐ International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... \$670.00
  - ☒ International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) ..... \$96.00

**ENTER APPROPRIATE BASIC FEE AMOUNT =**

\$96.00

Surcharge of \$130.00 for furnishing the oath or declaration later than months from the earliest claimed priority date (37 CFR 1.492 (e)). ☐ 20 ☐ 30

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	21 - 20 =	1	x \$18.00
Independent claims	3 - 3 =	0	x \$78.00

\$18.00

\$0.00

\$0.00

Multiple Dependent Claims (check if applicable).

**TOTAL OF ABOVE CALCULATIONS =**

\$114.00

Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) (check if applicable). ☐

\$0.00

**SUBTOTAL =**

\$114.00

Processing fee of \$130.00 for furnishing the English translation later than months from the earliest claimed priority date (37 CFR 1.492 (f)). ☐ 20 ☐ 30 +

\$0.00

**TOTAL NATIONAL FEE =**

\$114.00

Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) (check if applicable). ☒

\$40.00

**TOTAL FEES ENCLOSED =**

\$154.00


Amount to be: refunded \$ charged \$

- ☒ A check in the amount of \$154.00 to cover the above fees is enclosed.
- ☐ Please charge my Deposit Account No. in the amount of to cover the above fees.
- ☐ A duplicate copy of this sheet is enclosed.
- ☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. 08-2461 A duplicate copy of this sheet is enclosed.

**NOTE:** Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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(973) 331-1700

  
SIGNATURE  
KIRK M. MILES, ESQ.  
NAME  
37,891  
REGISTRATION NUMBER  
MARCH 1, 2000  
DATE

09/486839

428 Rec'd PCT/PTO 01 MAR 2000

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**  
**AS THE DESIGNATED/ELECTED OFFICE UNDER 35 U.S.C. § 371**

Applicant: Achari, et al.  
Application No.: Unassigned (§ 371 Filing of  
PCT/US98/18953)  
International Filing Date: 11 September 1998  
Priority Date: 11 September 1997  
Examiner: M. Moezie (Anticipated)  
Docket: 719-75 PCT/US  
Title: INTRANASAL FORMULATION  
CONTAINING SCOPOLAMINE  
AND METHOD OF TREATING  
MOTION SICKNESS  
Date: March 1, 2000

Assistant Commissioner for Patents  
Washington D.C. 20231

Label No. EJ094852526US  
I hereby certify that on the date indicated below, I deposited  
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By: B. Kemmler

Attn: DO/US

**LETTER OF CLARIFICATION REGARDING SUBMISSION**  
**OF COPY OF DECLARATION ACCOMPANING A FILING**  
**UNDER 35 U.S.C. § 371**

The present paper is submitted in conjunction with entry into the U.S. National  
Phase under 35 U.S.C. § 371 for the above referenced PCT International application. The  
original PCT International Application was filed on September 11, 1997 in the

U. S. Patent and Trademark Office acting as the receiving office under the PCT. An original Declaration executed by each of the named inventors herein was submitted along with the original international application as filed in the U.S. Patent and Trademark Office as the Receiving Office on September 11, 1997. Accordingly, submitted herewith is a copy of the combined Declaration and Power of Attorney as submitted in connection with the original international application.

Additionally, an assignment document including a cover sheet was also submitted in connection with the original filing of the International Application on September 11, 1997. Applicants' undersigned representative, however, has not received a notification regarding the recordation of such Assignment. Accordingly, a copy of the assignment document is being re-submitted for recordation at the U.S. Patent and Trademark Office.

Any questions regarding this submission should be directed to Applicants' undersigned representative who can be reached by telephone at (973) 331-1700.

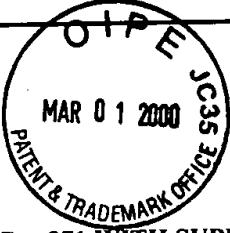
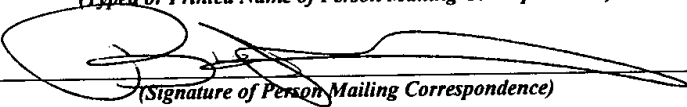
Respectfully submitted,



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03-02-00 09/486830 PCT #

<b>CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)</b>			Docket No. 719-75 PCT/US	
Applicant(s): ACHARI et al.				
Serial No. PCT/US98/18953	Filing Date 11 SEPTEMBER 1997	Examiner 416 Rec'd PCT/PTO	Group Art Unit 01 MAR 2000	
Invention: INTRANASAL FORMULATION CONTAINING SCOPOLAMINE AND METHOD OF TREATING MOTION SICKNESS				
				
I hereby certify that this <u>FILING UNDER 35 U.S.C. 371 WITH SUPPORTING DOCUMENTS</u> (Identify type of correspondence)				
is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: The Assistant Commissioner for Patents, Washington, D.C. 20231 on <u>March 1, 2000</u> (Date)				
Barbara Kemmlein (Typed or Printed Name of Person Mailing Correspondence)				
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